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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,705	02/04/2002	Charles L. Sawyers	30435.53USD7	8401
26941	7590	08/23/2004	EXAMINER	
MANDEL & ADRIANO 55 SOUTH LAKE AVENUE SUITE 710 PASADENA, CA 91101			TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/29/03

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/067,705	SAWYERS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/29/03</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

### DETAILED ACTION

Applicants' Preliminary Amendment, filed 2/4/04, canceling claims 2-20 has been entered. Claim 1 is pending and under current examination.

Note: This application has been filed as a divisional application of App. No. 09/08,951,143. However, as no restriction appears in the '143 Application, it is inappropriate to designate this application as a divisional application and the instant application would be considered a continuation of the '143 Application.

### *Priority*

The priority information in the first paragraph of the specification should be updated to reflect that U.S. App. No. 09/567,202 is now U.S. Pat. No. 6,365, 797 B1, U.S. App. No. 08/951,143 is now U.S. Pat. No. 6,107,540 and U.S. App. No. 08/732,676 is abandoned. Furthermore, the priority information should be updated to reflect the relationship between the applications (*e.g.*, continuation, divisional, etc.). Appropriate correction is required.

### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it lists 08/732,676 as a U.S. provisional Application. This case is a non-provisional case.

### *Information Disclosure Statement*

Applicants' IDS, filed 9/29/03, has been considered and made of record.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-11 of U.S. Patent No. 6,365,797 B1 (published April 2, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because the mice and methods in the '797 patent result in the instantly claimed immune deficient mouse having a human prostate cancer xenograft of locally advanced or metastatic

prostate cancer. The mice of the '797 patent are SCID mice with a human prostate cancer xenograft, and the methods of the '797 patent are directed to making such mice. Thus, it would have been obvious to the skilled artisan at the time of the present invention to produce the mice of the instant invention, given the methods and mice of the '797 patent.

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-4, 7-13, 16 and 17 of U.S. Patent No. 6,107,540 [published August 22, 2000]. Although the conflicting claims are not identical, they are not patentably distinct from each other because the mice and methods of the '540 patent result in the instant claimed immune deficient mouse having a human prostate cancer xenograft of locally advanced or metastatic prostate cancer. The mice of the '540 mice are chimeric, SCID mice having a human prostate cancer xenograft, and the methods of the '540 patent are directed to making such mice. Thus, it would have been obvious to the skilled artisan at the time of the present invention to produce the mice of the instant invention, given the methods and mice of the '540 patent.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims 21-27 of copending Application No. 10/062,925. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the immune deficient mice having a human prostate cancer xenograft of locally advanced or metastatic prostate cancer of the instant invention encompass the mouse models of human prostate cancer of the '925 Application. Thus, it would have been obvious for a skilled artisan, at the time the present invention was claimed, to produce the mice of the instant invention given the mice of the '925 Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims 21-27 of copending Application No. 10/062,738. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods and mice claimed in the '738 Application produce the immune deficient mice having a human prostate cancer xenograft of locally advanced or metastatic prostate cancer of the instant invention. The methods of the '738 application are directed to methods of producing a chimeric mouse that models human prostate cancer comprising implanting human prostate cancer tissue into an immunocompromised mouse. Thus, the immune deficient mice Thus, it would have been obvious for a skilled artisan, at the time the present invention was claimed, to produce the mice of the instant invention given the methods of the '738 Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Liu *et al.* [*Int. J. Cancer*, 65:85-89(1996), cited in Applicants' IDS filed 5/9/02].

The claim is directed to an immune deficient mouse having a human prostate cancer xenograft of locally advanced or metastatic prostate cancer.

Liu teach mouse models of human prostate cancer, LuCaP 23.1 and teach that the prostatic carcinoma xenograft originated from a lymph-node metastasis. See 85, 1<sup>st</sup> column, 2<sup>nd</sup> ¶. Liu teach that the LuCaP 23.1 xenograft was maintained and passaged in BALB/c/*nu/nu* mice [see Materials and Methods section].

Accordingly, Liu anticipate the claim.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pretlow [*J. of Nat. Canc. Inst.*, 85:394-398 (1993), cited in Applicants' IDS filed 5/9/02].

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Pretlow teach chimeric nude mice comprising human primary prostatic carcinomas. See pp. 394-395, Materials and Methods section.

Accordingly, Pretlow anticipate the claimed invention.

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

*tnt*

Thaian N. Ton  
Patent Examiner  
Group 1632

*Joe Waitach*  
AUG 32